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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/574,460	05/18/2000	Michael A. Apicella	875.009US1	6817

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/574,460

Applicant(s)

APICELLA ET AL.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 11, 12 and 18-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 11, 12 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Prosecution Application

The request filed on September 11, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/574,460 is acceptable and a CPA has been established. An action on the CPA follows.

The after final amendment filed on July 22, 2002, amending claims 6-8, 11-12 and 18-21 and adding claim 22, has been entered.

The preliminary amendment filed on November 1, 2002, adding claims 23-29, has been entered.

Claims 6-8, 11-12 and 18-29 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8, 11-12, 18-21 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. in view of Alexander et al.

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McLaughlin et al. (form PTO-1449) teach a process for production of *H. influenzae*-specific lipooligosaccharides (or complex carbohydrates) using a lipooligosaccharide-synthesis gene (*lsg*) from *H. influenzae* (pages 166-167). McLaughlin et al. teach that the various sugar transferases express from the *lsg* are responsible for the modification of the existing *E. coli* LPS (page 172). McLaughlin et al. also teach that the lipooligosaccharides of *H. influenzae* are important virulence factors for this pathogen.

The difference between the reference of McLaughlin et al. and the instant invention is that the reference of McLaughlin et al. does not teach a process of making the lipooligosaccharide using a *rfe* enzyme.

Alexander et al. (form PTO-1449) teach an *E. coli* *rfe* and that the enzyme is essential for the first step in the biosynthesis of lipooligosaccharide (page 7079).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make lipooligosaccharides with a *E. coli* K-12 expressing an *E. coli* *rfe* and a *H. influenzae* *lsg*. The motivation of making *H. influenzae*-specific lipooligosaccharides is to produce the lipooligosaccharide in large amounts to effectively obtain oligosaccharides, useful in developing vaccines and in identification of the *H. influenzae* bacteria itself. One of ordinary skill in the art would have had a reasonable expectation of success since recombinant technology is performed routinely in the art.

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Claims 11, 22 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. in view of Alexander et al., further in view of Swierzko et al.

The references of McLaughlin et al. and Alexander et al. in combination teach a process of making lipooligosaccharides with a lsg gene and a rfe gene with a *E. coli* bearing a terminal heptose molecule, as discussed above.

The difference between the combined teaching of McLaughlin et al. and Alexander et al. and the instant invention is that the reference of the combined teachings does not teach a process of making the lipooligosaccharide using a *Salmonella minnesota* bacterium.

Swierzko et al. teach that *S. minnesota* bears a terminal heptose molecule and teaches the use of this bacterium in synthesizing lipooligosaccharides (pages 3216-3217). *S. minnesota* is an useful bacteria because of their rapid growth in the laboratory.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make lipooligosaccharides with a *S. minnesota* expressing an *E. coli* rfe and a *H. influenzae* lsg. The motivation of making using *S. minnesota* is out of conveniences since *S. minnesota* grow rapidly and are used in the art for lipooligosaccharides synthesis. One of ordinary skill in the art would have had a reasonable expectation of success since *S. minnesota* are easy to work and well known in the art.

Response to Arguments

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Applicant's arguments filed October 31, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8, 11-12 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin et al. in view of Alexander et al.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine the reference of Alexander et al. and McLaughlin et al. is to introduce the rfe gene to the teachings of Alexander et al. since the rfe enzyme is essential for the first step in the biosynthesis of lipooligosaccharides.

Applicants argue that a proper suggestion or motivation to combine or modify the cited documents have not been provided because neither of the references teach that the *rfe* enzyme is essential for the first step in the biosynthesis of lipooligosaccharides. The examiner disagrees. Alexander et al. do teach the *rfe* is the structural gene that catalyzes the transfer of a GlcNAc onto an Undecaprenol phosphate, the first step in enterobacterial common antigen biosynthesis (page 7079, 2nd column).

Applicants also argue that the cited documents fail to teach or suggest all of the elements of the instant invention because Alexander et al. and McLaughlin et al. do teach how a chimeric complex carbohydrate might be assembled, that *rfe* can be upregulated in expression to allow assemble of the chimeric carbohydrates on the E. coli LPS core antigen, or that an *rfe* gene adds an acceptor molecule to the terminal heptose of a gram-negative bacteria. The examiner disagrees. As stated in the office action, McLaughlin et al. teach the production of a chimeric LPS. Applicants have stated on page 7, Alexander et al. teaches the role of *rfe* gene in the assembly of the O-antigen in E. coli. The instant invention is not drawn to an upregulated expression of the *rfe* gene. The *rfe* gene can be simply inserted into the production cell. Therefore, one of ordinary skill in the art would have been motivated to use the *rfe* gene to start the first step of antigen biosynthesis.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 8:00 A.M. to 4:30 P.M weekdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner

November 15, 2002



PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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